REMARKS

In an Official Action dated March 10, 2004, the Examiner rejected claims 45, 48-50, 69 and 72 as anticipated by Ridderheim 4,955,870. In addition, the Examiner rejected the pending claims under obviousness-type double patent over a number of Applicants' patents alone or in combination with Alter 4,919,652. Applicants request that the Examiner reconsider the rejections in light of the following discussion.

Claims 45, 48-50, 69 and 72 are patentable over Ridderheim 4,955,870

As discussed below, Ridderheim is not directed to a device having a needle assembly that includes a biasing element, which is connectable to a barrel. Instead, Ridderheim '870 discloses a device in which the spring is located in the plunger, not in the needle assembly. Therefore, the Ridderheim device requires an exacting connection between the plunger tip and the needle hub to ensure retraction, and complicates the production of the device.

Referring to Fig. 1, Ridderheim discloses a syringe having a barrel 16 and a plunger 14 that slides within the barrel. The plunger includes a frangible tip 84 that is connected a spring 56 in the plunger. The spring 56 is maintained in tension so that the spring biases the plunger tip 84 in tension.

A needle assembly 12 attached to the forward end of the barrel 16 has a mating means 86 configured to cooperate with a protrusion 92 on the end of the plunger tip 84. The needle assembly includes a plug 64 connected to the barrel 16 that is detachably connected to the mating means 86 of the needle assembly 12. In this way, at the end of the injection stroke, the protrusion 92 on the plunger engages the mating means 86 of the needle assembly. By pushing further on the plunger, the matting means 86 and needle are ripped from the plug 64 freeing the needle for retraction. At the same time, the tip of the plunger is fractured, so that the needle is retracted into the plunger.

In contrast to the Ridderheim structure, Applicants' device includes a needle assembly in which the needle assembly is separate and can be attached to the barrel prior to use. Further, in Applicants' device, the needle assembly includes the biasing element, rather that having the biasing element disposed in the plunger.

There are numerous disadvantages to the Ridderheim structure. First, by using a spring under tension, the plunger becomes much more complicated to manufacture. The tip cannot be molded integrally with the plunger stem, because doing so would make it impossible to attach the spring to the plunger and the plunger tip. Furthermore, the plunger tip must be held in a delicate balance. The connection between the plunger tip and the plunger stem must be sufficient to withstand the tension of the spring and the hydraulic forces acting against the tip during an injection, while at the same time the tip must be able to break free from the plunger easily to cause retraction.

In addition to these complications, the Ridderheim device relies on a connection between the plunger tip and the needle mating means 86. If the connection fails, the needle will not retract. More specifically, at the end of the injection stroke, the plunger tip is fractured from the plunger stem, and the mating means 86 and needle are broken from the needle plug 64. As soon as the plunger tip is fractured, the tip will retract regardless of whether the needle is attached. In other words, it the plunger tip does not adequately connect with the mating means 86 the needle will not retract. Therefore, the system must ensure a significant connection between the plunger tip and the mating means 86, which must withstand the force of the needle being suddenly jerked rearwardly upon retraction.

If any of the foregoing aspects of the Ridderheim device does not operate properly, the needle does not retract. In other words, the first end of the spring and the outer end of the plunger must stay connected. The second end of the spring must stay

connected to the plunger tip. The plunger tip must stay connected to the plunger stem before use and during an injection. The plunger tip must break from the plunger stem at the end of an injection. The needle must break from the plug 64 at the end of an injection and the plunger tip must engage the needle mating means 86 and securely hold the mating means during retraction. This is a lot of critical requirements for a device. Therefore, it would be difficult to expect the device to reliably operate on mass production scale, and even more difficult to do so inexpensively.

Further still, near the end of an injection stroke, the protrusion 92 on the end of the plunger begins to block the end of the needle before all of the fluid is expelled from the barrel. Therefore, the needle 12 must include a complicated series of holes 80 to allow the fluid in the barrel to flow through the needle when the plunger nears the end of an injection.

As can be seen, there are numerous disadvantages to the Ridderheim structure that complicate the manufacture, assembly and reliability of the device. Furthermore, there is nothing in Ridderheim that teaches or suggests altering the Ridderheim structure to be like Applicants' structure. In fact, there is nothing in Ridderheim that suggests addressing the advantages of having a structure like Applicants'. Specifically, Applicants' structure allows the user to select the desired needle and attach the needle assembly to the barrel. Ridderheim does not allow the user to do this. As shown in Fig. 1, the Ridderheim structure requires that the needle 12 be threaded into the barrel from the *inside*. See Fig. 2. It is difficult to imagine how a medical professional could reach down through the inside of the barrel and screw a needle assembly into the barrel prior to use. Clearly, the needle assembly must be attached during manufacture.

Turning now to the claim language, features that distinguish Applicants' device from the Ridderheim device are reflected in the claims. Specifically, claim 1 and

69 recite a medical device having a hollow barrel having a forward end and a first connector, and a needle assembly having a second connector that is cooperable with the first connector to attach the needle assembly to the barrel. Further, the needle assembly includes a biasing element biasing the needle toward the retracted position. As discussed above, the Ridderheim device does not include a needle assembly that has a biasing element; the biasing element is in the plunger. Since this difference leads to significant advantages over the Ridderheim and since Ridderheim does not teach or suggest such features, Applicants request that the Examiner reconsider the rejection of claims 1 and 69 over Ridderheim, along with dependent claims 48-50 and 72.

Double-Patenting Rejections

The Examiner rejected claims 45, 50-51, 56-58, 60-64 and 66-69 under obviousness-type double patenting over U.S. Patent No. 6,179,812. However, on March 4, 2004 Applicants submitted a terminal disclaimer for U.S. Patent No. 6,179,812, and there is no indication that the terminal disclaimer was deficient in any manner. Accordingly, Applicants request that the Examiner reconsider the double patenting rejection over 6,179,812.

Based on obviousness-type double patenting, the Examiner also rejected claims 45-48, 50-54, 56-58, 60-64 and 66-73 over U.S. Patent No. 4,994,034 and claims 45-47, 50-53, 56-59, 61-64 and 67-73 over U.S. Patent No. 5,407,431. Since Applicants have already paid for the terminal disclaimer previously filed, and since these new double-patenting rejections are not based on amendments to the claims, Applicants request that they be permitted to file a terminal disclaimer to overcome the double patenting rejection based on U.S. Patent Nos. 4,994,034 and 5,407,431 after the remaining rejections are resolved.

Although Applicants are willing to file a terminal disclaimer regarding U.S.

Patents No. 4,994,034 and 5,407,431, Applicants request that the Examiner reconsider the rejection of claims 45-47, 50-53, 56-58, 60-64 and 66-73 over U.S. Patent No. 5,188, 599. As discussed below, there are several patentable distinctions between claims 1-17 of the '199 patent and the pending claims.

The claims of the '199 patent include many features that are not recited in the pending claims. The features are patentable distinctions. Specifically, claim 1 of the '199 patent recites a spring holder and spring holding means. Pending claims 45, 51 and 69 do not recite such elements. Further, claim 1 of the '119 patent specifies that the spring holder has a lip and the spring holding means has extending resilient fingers with interior and inferiorly positioned hooks. Nothing in claims 45, 51 or 69 even remotely suggests such features. In fact, none of the pending claims recites any structure resembling resilient fingers having hooks. Further still, pending claims 57 and 63 are method claims that do not recite any of the above-mentioned features of '199 claim 1. Additionally, claim 1 of '199 recites that the spring holding means is lockable to the barrel to prevent removal of the spring holding means from the barrel. Again, nothing in any of the claims recites locking the needle assembly to the barrel.

Claims 12 and 15 of the '199 patent include features similar to those discussed above that distinguish the '199 claims from the pending claims. Further still claims 12 and 15 recite further features that distinguish them from the pending claims. For instance, claim 12 recites that the plunger means includes tapered shoulders which engage oppositely and complementing shoulders of the resilient fingers. Claim 15 recites barrel means including slots and a groove sized and positioned within an interior of the barrel means to receive extending tabs of the spring housing in locking engagement. These differences further distinguish claims 12 and 15 from the pending claims.

Claim 16 also recites spring holding means that can be easily attached to

the barrel and lockable thereto. Again, as discussed above, nothing in the pending claims suggests attaching and locking the needle to barrel.

Claim 17 recites a feature wherein the plunger has a dissociable end and a piston, and further recites that the plunger end is separated while the plunger piston slides rearwardly from a first forward position to a second rearward position. Nothing in the pending claims relates to such features.

In light of the foregoing discussion, Applicants believe that the claims are patentably distinct from claims 1-17 of the '199 patent based on the features on claims 1-17 that distinguish the claims from the pending claims. Further still, there are features in the pending claims that are not recited in claims 1-17 of '199. For instance, claims 45, 51 and 63 specifically recite that the barrel includes a first connector and the needle assembly includes a second connector that is cooperable with the first connector to connect the needle assembly to the barrel. The '199 claims recite a spring holding means that is attachable to the barrel, however, the '199 claims do not specify connectors on a needle assembly and the barrel. Instead, the '199 claims are broad enough to cover a spring housing that is somehow attached to the barrel without separate connectors. In other words, the '199 claims are broad enough to cover a structure in which the spring holding means is glued or welded to the barrel during manufacture. In contrast, the pending claims recite features directed to permitting the needle assembly to be attached to the barrel prior to use if desired. Accordingly, not only are there significant features in the '199 claims that are not recited in the pending claims, there are also features in the pending claims that are not recited in the '199 claims. In light of all of these differences, Applicants request that the Examiner reconsider the obviousness-type double patenting rejection over the '199 patent.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned

attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **THREE** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

September 9, 2004
Date of Certificate

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